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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/549,914

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Yasumi Yugari

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WENDEROTH, LIND & PONACK, L.L.P.

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SUITE 800

WASHINGTON, DC 20006-1021

EXAMINER

FRAZIER, BARBARA S

ART UNIT

PAPER NUMBER

1611

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/549,914	Applicant(s) YUGARI ET AL.	
	Examiner BARBARA FRAZIER	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/29/08.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-10 are pending in this application.

Specification

2. The disclosure is objected to because of the following informalities: the specification recites, "Bacillus coagulant (e.g. LACROSSE (Trade name)) may be added. This appears to be a typographical error for the term "Bacillus coagulans".

Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The rejection of claims 1-10 under 35 U.S.C. 102(b) as being anticipated by Nakashima et al (US Patent 5,126,143) is withdrawn in view of Applicant's amendment to claim 1.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakashima et al (US Patent 5,126,143) in view of Farmer (US Patent 6,461,607).

The claimed invention is drawn to a food composition according to claim 1:

1. Food composition for lowering blood concentration of low-molecular-weight nitrogen-containing compounds, which comprises: a foodstuff with a) more than 5% by weight of water- soluble indigestible polysaccharides relative to a total amount of dried foodstuff, said indigestible polysaccharides capable of being decomposed by intestinal bacteria, and b) *Bacillus coagulans*, said foodstuff having protein component of 50% or less.

Nakashima et al teach a bowel-movement-improving food containing 10-50% by weight of dietary fibers based upon the whole product (see claim 1). The amount of

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protein in the food is less than 8%; amounts of 6% and 5.4% casein are exemplified (see, for example, Examples 1 and 4). The dietary fibers are decomposed by intestinal microorganisms (see Examples 1, 4 and 5).

Nakashima et al do not specifically teach the presence of *Bacillus coagulans* in the food.

Farmer teaches the utilization of lactic acid-producing bacteria, preferably *Bacillus coagulans*, for control of gastrointestinal tract pathogens and their associated diseases (abstract), and that *Bacillus coagulans* strains have been used as general nutritional supplements and agents to control constipation and diarrhea in humans and animals (col. 14, lines 50-53).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to add *Bacillus coagulans* to the composition of Nakashima et al; thus arriving at the claimed invention. One skilled in the art would have been motivated to do so because the addition of *Bacillus coagulans* provides the benefits of controlling constipation and diarrhea, as taught by Farmer. Additionally, it is prima facie obvious to combine two compositions, each of which is taught by the prior art, to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. See MPEP 2144.06. One would reasonably expect success from the addition of *Bacillus coagulans* as taught by Farmer to the composition taught by Nakashima et al because both references are drawn to improving bowel movements.

Regarding the phrase “for lowering blood concentration of low-molecular-weight nitrogen-containing compounds”, said phrase describes an intended use for the food, and is not given patentable weight.

Regarding claim 2, Nakashima et al. disclose foods having more than 5% indigestible polysaccharides - see Example 1, which has 25% dietary fibers (18 parts polydextrose and 6.9 parts pectin, relative to 100.3 total parts). Protein amounts of less than 8% protein are also exemplified (see Example 1, which has 6% casein – 6 parts sodium casein, relative to 100.3 total parts).

Regarding claim 3, Nakashima et al. disclose that dietary fibers which may be used are polydextrose and pectin (see col. 3, lines 20-22 and claim 1).

Regarding claim 4, Nakashima et al. disclose that the food contains a mixture of polydextrose and pectin, wherein said mixture is comprised of 1/2 to 3/4 polydextrose and 1/2 to 1/4 pectin. This reads on Applicant's ratio of 0.05 to 100 parts by weight of pectine to 100 parts of polydextrose.

Regarding claims 5 and 6, Nakashima et al. disclose that the foods may contain vitamins (col. 4, lines 32-38).

Regarding claims 7-10, Nakashima et al. disclose that the food may be in the form of the wafer; the term “wafer” reads on a reasonable interpretation of either “biscuit”, “cookie” or “bread”.

Conclusion

No claims are allowed at this time.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BARBARA FRAZIER whose telephone number is (571)270-3496. The examiner can normally be reached on Monday-Thursday 9am-4pm EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BSF

/Sharmila Gollamudi Landau/
Supervisory Patent Examiner, Art Unit 1611